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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,100	02/05/2004	Ulrich Pessara	VOSS-P01-007	3295

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/773,100	PESSARA ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

ELECTION/RESTRICTIONS

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claim 1 link(s) inventions I-IV set forth below. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Group I: Claims 1-28 drawn to a method for screening a collection of nucleic acid molecules for a desired property of the nucleic acid or of a (poly)peptide encoded thereby, classified in class 702, subclass 019. If this Group is elected, then the below summarized three specie elections are also required.

Group II: Claims 29-30 drawn to a method for the improvement of the binding properties of the (poly)peptide encoded by the DNA identified or isolating in the screening process,

classified in class 702, subclass 019. If this Group is elected, then the below summarized three specie elections are also required.

Group III: Claim 31 drawn to a method for the further modification of (poly)peptide as a leading structure, classified in class 702, subclass 019. If this Group is elected, then the below summarized three specie elections are also required.

Group IV: Claim 32 drawn to a method for the manufacture of a pharmaceutical composition, and formulating of the substance obtained with a pharmaceutical acceptable carrier or diluent, classified in class 702, subclass 019. If this Group is elected, then the below summarized three specie elections are also required.

The inventions are distinct and divergent, each from the other because of the following reasons:

While the inventions of Group I and Group II are related, they consist of distinct steps and therefore have different modes of operation, different functions, or different effects. In the instant case the inventions of Groups I and II have different functions. Group I is drawn to a method for screening a collection of nucleic acid molecules for a desired property of the nucleic acid or of a (poly)peptide encoded thereby, whereas Group II is drawn to method for the improvement of the binding properties of the (poly)peptide encoded by the DNA identified or isolating in the screening process. Critical limitations of Group II that are separate and distinct from Group I include the identification of the (poly)peptide binding sites, molecular modeling, and modification of the (poly)peptide.

While the inventions of Group III and Group IV are related, they consist of distinct steps and therefore have different modes of operation, different functions, or different effects. In the

instant case the inventions of Groups III and IV have different functions. Group III is drawn to a method for the further modification of (poly)peptide as a leading structure, whereas Group IV is drawn to a method for the manufacture of a pharmaceutical composition, and formulating of the substance obtained with a pharmaceutical acceptable carrier or diluent. Critical limitations of Group III that are separate and distinct from Group IV include a modified site of activity, a decrease toxicity, decreased side effects, and modified pharmacokinetic parameters, to name a few.

The inventions of Groups [I and II] and Groups [III and IV] are distinct and divergent for the following reasons: Groups [I and II] are drawn to a method for screening a collection of nucleic acid molecules for a desired property of the nucleic acid or of a (poly)peptide encoded thereby, and for the improvement of the binding properties of the (poly)peptide encoded by the DNA identified or isolating in the screening process; Groups [III and IV] are drawn to a method for the further modification of (poly)peptide as a leading structure, and for the manufacture of a pharmaceutical composition and formulating of the substance obtained with a pharmaceutical acceptable carrier or diluent. Critical limitations of Group I that are separate and distinct from Groups [III and IV] include the automated picking of cells and automated screening by means of a robot. Critical limitations of Group II that are separate and distinct from Groups [III and IV] include the identification of the (poly)peptide binding sites, molecular modeling, and modification of the (poly)peptide.

Thus, the search for these groups together would present an undue search burden as they are directed to methods that are generally distinct and separate.

SPECIE ELECTION REQUIREMENT

This application contains claims directed to patentably distinct and divergent species of the claimed inventions. If Group I, II, III, or IV is elected, the applicant is further required to make the following three specie elections for purposes of examination:

Specie A: Species of nucleic acid molecules are cited in claim 3, which are generally separately classified and published, and thus document undue search burden if searched together. Thus applicants are required to select a type of nucleic acid molecule from those listed in claim 3.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 are generic to the above species.

Specie B: Species of functional screening are cited in claims 25 and 26. The technical literature search for methods of screening for enzymatic, pharmacological, and therapeutic properties is not coextensive, and thus document undue search burden if searched together. Similarly, the technical literature search for methods of screening for activation or suppression of a reporter system or the secretion of a protein is not coextensive. Thus applicants are required to select one of the following:

i. Screening for an enzymatic property

ii. Screening for a pharmacological property

iii. Screening for a therapeutic property

iv. Screening for activation or suppression of a reporter

v. Screening for the secretion of a protein

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-24 are generic to the above species.

Specie C: Species of transfection of cells are cited in claim 19. The technical literature describing transfection by calcium phosphate, electroporation, and lipofactors is not coextensive, thus applicants are required to select one type of transfection of cells from those listed in claim 19.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-18, and 20-32 are generic to the above species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct and divergent, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other inventions.

Because these inventions are distinct and divergent for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the inventions to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected inventions, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am through 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
12/1/05